DMB

Display Date 12·1·98
Publication Date 12·2
Certifier C. WMS·DAY

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name ***of*** Committee: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee; To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 18, 1998.10:15 a.m. to 5:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Michael G. Bazaral, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8609, ext. 140, or FDA Advisory Committee Information Line, 1–800-741-8 138 (301-443-0572 in the Washington, DC area), code 12624. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on general issues related to the classification of tracheal gas insufflation (TGI) devices used to provide part or all of the breathing gas for treatment of respiratory failure or respiratory insufficiency. The use of the TGI catheter, tube or lumen only for supply of fresh gas distinguishes TGI from common tracheal

N 2

tubes and tracheotomy tubes, in which the gas flow alternates between inhalation and exhalation. The draft versions of five questions FDA will ask the committee to address are listed as follows:

1. For the evaluation of effectiveness of specific TGI systems as an adjunct to ventilation of adults, is reduction of minute ventilation (or PCO_2) without appreciable increase in end-expiratory lung volume or pressure a sufficient endpoint? Is this the correct endpoint?

2. For ventilation of adults, is there now sufficient understanding of TGI to be reasonably sure that TGI, with adequate monitoring and other understood safety provisions, will not have worse outcomes? Or does TGI raise concerns that will require that FDA review data on patient outcomes?

3. Are there special considerations about the data FDA should review for TGI submissions in relation to ventilation of children, infants, newborns, or premature infants?

4. What are the minimum system functions that include all the functions needed to provide TGI for clinical use as an adjunct to or replacement for conventional ventilation?

5. What specific safety provisions are important? Is distal pressure monitoring essential?

Procedure: On December 18, 1998, from 12:15 p.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present information or views, orally or in writing, on issues pending before the committee. Written submissions must be made to the contact person by December 11, 1998. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m., and between approximately 4 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 11, 1998, and submit a brief statement of the general nature of the arguments they wish to present, the names and addresses of the proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 18, 1998, from 10:15 a.m. to 12:15 p.m., the meeting will be closed to permit FDA to present trade secret and/or confidential commercial information (5 U.S.C. 522 b(c)(4)) regarding pending issues and applications.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 24, 1998

Michael A. Friedman
Deputy Commissioner for Operations

[FR Dot, 98-???? Filed ??-??-98: 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL